

U.S.S.N. 09/269,903
Filed: May 6, 1999
RESPONSE TO OFFICE ACTION
UNDER 37 C.F.R. § 1.116

A Petition for an Extension of Time for One Month, up to June 27, 2001, and the appropriate fee are enclosed. It is believed that no additional fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-1868.

In the claims

13. (Twice amended) The composition of claim 1 wherein the pellets are administered in a starch capsule coated with a combination of polymethacrylates [that] which capsule is so designed to disintegrate and release the pellets in the terminal ileum or in the colon.

15. (Twice amended) A method for making a composition comprising pellets, wherein each pellet comprises an inner core comprising a drug which possesses
(a) a free acid group which can be converted into an alkali metal salt, and
(b) a pKa in the range 2.0 to 9.0,
wherein the inner core of the pellets is coated with a rate-controlling membrane that determines drug release, wherein the drug is present as a salt that displays higher solubility at pH 4.5 to 8.0 than the corresponding compound containing a free acid group, and
wherein the composition is adapted to prevent release of drug until the composition reaches the terminal ileum or the colon following oral administration of the composition, the method comprising

making a salt of the drug, [and]
coating the salt onto the inner cores, and
coating the rate-controlling membrane that determines drug release onto the salt.

21. (Once amended) The composition of claim 1 wherein the pellets are compressed into tablets which are coated with a material to prevent release of drug until the composition reaches the terminal ileum or the colon following oral administration of the composition.